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| EXAMINER | |
|---|---|
| BRISTOL, LYNN ANNE | |

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| 1643 | |

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/618,088 | JAFFEE ET AL. | |
| | Examiner | Art Unit | |
| | Lynn Bristol | 1643 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-112 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-112 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. It is noted that Applicants' specification teaches that mesothelin epitopes are distinguishable on the basis of whether they induce a CD4+ or CD8+ T-cell response vis-à-vis whether the peptide epitope is an MHC Class I-binding versus MHC Class II-binding epitope. The specification teaches that MHC Class I-binding epitopes are useful for activating CD8+ T cells and the latter for activating CD4+ T cells (see entire specification, especially p. 15, ¶43). Thus, on the basis on Applicant's separation of the epitopes into these two classes, the claims are grouped accordingly for purposes of restriction.

### *Restrictions*

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   1. Claims 1-17 and 110, drawn to methods for inducing a T-cell response to a mesothelin-overexpressing tumor in a patient with or having had the tumor comprising administering a vaccine comprising a polypeptide comprising an MHC Class I-binding epitope of mesothelin, class 424, subclass 277.1.
   2. Claim 18, drawn to methods for inducing a T-cell response to a mesothelin-overexpressing tumor in a patient with or having had the tumor comprising administering a vaccine comprising a polypeptide comprising an MHC Class II-binding epitope of mesothelin, classified in class 424, subclass 277.1.

3. Claims 19 in part, 20 and 21, drawn to methods for inducing a T-cell response to a mesothelin-overexpressing tumor cell in a patient at risk of developing the tumor comprising administering a vaccine comprising a polypeptide comprising an MHC Class I-binding epitope of mesothelin, classified in class 424, subclass 277.1.

4. Claims 19 in part, 20 and 21, drawn to methods for inducing a T-cell response to a mesothelin-overexpressing tumor cell in a patient at risk of developing the tumor comprising administering a vaccine comprising a polypeptide comprising an MHC Class II-binding epitope of mesothelin, classified in class 424, subclass 277.1.

5. Claims 22-38 and 111, drawn to methods for inducing a T-cell response to a mesothelin-overexpressing tumor in a patient with or having had the tumor comprising administering a vaccine comprising a polynucleotide encoding a polypeptide comprising an MHC Class I-binding epitope of mesothelin, classified in class 514, subclass 44 or class 536, subclass 23.5.

6. Claim 39, drawn to methods for inducing a T-cell response to a mesothelin-overexpressing tumor in a patient with or having had the tumor comprising administering a vaccine comprising a polynucleotide encoding a polypeptide comprising an MHC Class II-binding epitope of mesothelin, classified in class 514, subclass 44 or class 536, subclass 23.5.

7. Claims 40 in part, 41 and 42, drawn to methods for inducing a T-cell response to a mesothelin-overexpressing tumor cell in a patient at risk of developing the tumor comprising administering a vaccine comprising a polynucleotide encoding a polypeptide comprising an MHC Class I-binding epitope of mesothelin, classified in class 514, subclass 44 or class 536, subclass 23.5.

8. Claims 40 in part, 41 and 42, drawn to methods for inducing a T-cell response to a mesothelin-overexpressing tumor cell in a patient at risk of developing the tumor comprising administering a vaccine comprising a polynucleotide encoding a polypeptide comprising an MHC Class II-binding epitope of mesothelin, classified in class 514, subclass 44 or class 536, subclass 23.5.

9. Claims 43-53, drawn to methods for identifying tumor-expressed protein immunogens for anti-tumor vaccines comprising testing for CD4+ or CD8+ T cell response from patients having been vaccinated with the protein, classified in class 424, subclass 277.1.

10. Claims 54-58, drawn to methods of predicting responsiveness to tumor vaccines comprising mesothelin T-cell epitopes, the methods comprising testing for CD4+ or CD8+ T cell response from patients having been vaccinated with the epitope, classified in class 424, subclass 277.1.

11. Claims 59 in part, 60-66, 73, 75, 89, 92, 95 and 109, drawn to vaccines for inducing CD8+ T cells comprising polypeptides comprising MHC Class I-

binding epitopes of mesothelin and a carrier, classified in class 424, subclass 277.1.

12. Claims 59 in part, 60-66, 73, 75, 89, 92, 95 and 109, drawn to vaccines for inducing CD4+ T cells comprising polypeptides comprising MHC Class II-binding epitopes of mesothelin and a carrier, classified in class 424, subclass 277.1.

13. Claims 67 in part, 68-72, 74, 76 and 112, drawn to vaccines for inducing CD8+ T cells comprising polynucleotides encoding polypeptides comprising MHC Class I-binding epitopes of mesothelin and a carrier, classified in class 536, subclass 23.5.

14. Claims 67 in part, 68-72, 74, 76 and 112, drawn to vaccines for inducing CD4+ T cells comprising polynucleotides encoding polypeptides comprising MHC Class II-binding epitopes of mesothelin and a carrier, classified in class 536, subclass 23.5.

15. Claims 77, 87, 90 and 93, drawn to isolated polypeptides comprising an epitope of SEQ ID NOS: 1-6, classified in class 424, subclass 277.1.

16. Claims 78, 88, 91 and 94, drawn to fusion proteins comprising a first portion for an epitope of SEQ ID NOS: 1-6 and a second portion for a non-mesothelin segment, classified in class 424, subclass 185.1.

17. Claims 79-81, drawn to expression vectors and bacteria comprising the vectors encoding the polypeptides comprising an epitope of SEQ ID NOS: 1-6, classified in class 536, subclass 23.5.

18. Claims 82-84, drawn to expression vectors and bacteria comprising the vectors encoding the polypeptides comprising fusion proteins comprising a first portion for an epitope of SEQ ID NOS: 1-6 and a second portion for a non-mesothelin segment, classified in class 536, subclass 23.4.

19. Claim 85 in part, drawn to an antibody binding to the epitope of SEQ ID NO: 1, classified in class 424, subclass 139.1.

20. Claim 85 in part, drawn to an antibody binding to the epitope of SEQ ID NO: 2, classified in class 424, subclass 139.1.

21. Claim 85 in part, drawn to an antibody binding to the epitope of SEQ ID NO: 3, classified in class 424, subclass 139.1.

22. Claim 85 in part, drawn to an antibody binding to the epitope of SEQ ID NO: 4, classified in class 424, subclass 139.1.

23. Claim 85 in part, drawn to an antibody binding to the epitope of SEQ ID NO: 5, classified in class 424, subclass 139.1.

24. Claim 85 in part, drawn to an antibody binding to the epitope of SEQ ID NO: 6, classified in class 424, subclass 139.1.

25. Claim 86 in part, drawn to a T cell line binding the epitope of SEQ ID NO: 1, classified in class 435, subclass 344.1.

26. Claim 86 in part, drawn to a T cell line binding the epitope of SEQ ID NO: 2, classified in class 435, subclass 344.1.

27. Claim 86 in part, drawn to a T cell line binding the epitope of SEQ ID NO: 3, classified in class 435, subclass 344.1.

28. Claim 86 in part, drawn to a T cell line binding the epitope of SEQ ID NO: 4, classified in class 435, subclass 344.1.

29. Claim 86 in part, drawn to a T cell line binding the epitope of SEQ ID NO: 5, classified in class 435, subclass 344.1.

30. Claim 86 in part, drawn to a T cell line binding the epitope of SEQ ID NO: 6, classified in class 435, subclass 344.1.

31. Claims 96-100, drawn to methods for predicting tumor vaccine responsiveness for long-time survivability in a patient having received the tumor vaccine comprising measuring a delayed type hypersensitivity response to mesothelin, classified in class 424, subclass 277.1.

32. Claims 101-104, drawn to a recombinant mouse cell line comprising HPV-16 E6 and E7- and activated oncogene- transformed peritoneal cells, classified in class 435, subclass 354.

33. Claim 105 and 106, drawn to a recombinant mouse model comprising the recombinant mouse cell line comprising HPV-16 E6 and E7- and activated oncogene- transformed peritoneal cells, classified in class 800, subclass 10.

34. Claim 107, drawn to methods for testing drugs for treating a cancer in a mouse model comprising a recombinant mouse cell line comprising HPV-16 E6 and E7- and activated oncogene- transformed peritoneal cells, wherein said method comprises contacting the mouse with a test

substance and measuring tumor regression, diminution in ascites volume or longer survival, classified in class 800, subclass 3.

35. Claim 108, drawn to methods for testing drugs for treating a cancer in a comprising contacting the mouse with a test substance, injecting the mouse with a recombinant mouse cell line comprising human papilloma virus-16 oncogenes E6 and E7- (HPV-16 E6 and E7) and activated oncogene- transformed peritoneal cells, and measuring tumor regression, diminution in ascites volume or longer survival, classified in class 800, subclass 3.

3. The inventions are distinct and separate for the following reasons:

The polynucleotides of Groups 13, 14, 17 and 18 and the polypeptides of Groups 11, 12, 15, 16 and 19-24 are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function or effect. See MPEP § 806.05(j). In the instant case, the polynucleotide claims do not overlap the scope of the polypeptide claims and vice versa as evidenced by the distinct structures and functions of the claimed inventions. A polynucleotide's structure is comprised of linear, contiguous nucleotides while a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the DNA's function is to encode a protein while a protein's function is variable, and in this case, may serve as a CD4+ or a CD8+ T-cell inducing agent. Additionally, the

polynucleotides and polypeptides are not obvious variants of each other based on the distinct structures and functions of each as noted above. Lastly, the DNA and polypeptides have materially different functions as noted above.

Because these inventions are distinct for the reasons given above and the search required for Groups 13, 14, 17 and 18 is not required for Groups 11, 12, 15, 16 and 19-24, restriction for examination purposes as indicated is proper. While Groups 13, 14, 17 and 18 and Groups 11, 12, 15, 16 and 19-24 can be identically classified under U.S. Patent Classification guidelines, to search them together would present a search burden on the Examiner due to the extensive databases of non-patent literature. For example, claims in Groups 11, 12, 15, 16 and 19-24, drawn to polypeptides, must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated polypeptides are often disclosed without the benefit of sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the polynucleotide sequences must be searched in distinct nucleic acid sequence commercial databases. Thus, Groups 13, 14, 17 and 18 and Groups 11, 12, 15, 16 and 19-24 have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

4. The T-cell lines of Groups 25-30, the recombinant mouse cell line of Group 32 and the recombinant mouse model of Group 33 are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are

either not capable of use together or can have a materially different design, mode of operation, function or effect. See MPEP § 806.05(j). In the instant case, the cell line claims are not overlapping in scope amongst themselves or with the scope of the recombinant mouse model claims and vice versa as evidence by the distinct structures and functions of the claimed inventions. The T cell lines each comprise distinct clonotypic T cells differing in their antigen/epitope specificity with respect to the mesothelin epitope, the recombinant mouse cell line comprises a mixture of transformed peritoneal cells having been transformed by recombinant technology to introduce HPV-16 E6 and E7 with an activated oncogene, and the recombinant mouse expresses a tumor being derived from the transformed peritoneal cell line. Because the searching the T cell lines, the transformed peritoneal cell lines and the recombinant mouse tumor model would not be co-extensive due to their separate classifications, restriction for examination purposes as indicated is proper.

5. The methods of Groups 1-10, 31, 34 and 35 differ in the method objectives, method steps and parameters, intended populations and in the reagents used. The method inventions differ as follows: Group 1 requires vaccinating a patient having or having had surgically removed a mesothelin-overexpressing tumor with a polypeptide comprising an MHC Class I-binding epitope of mesothelin in order to induce a T cell response; Group 2 requires vaccinating a patient having or having had surgically removed a mesothelin-overexpressing tumor with a polypeptide comprising an MHC Class II-binding epitope of mesothelin in order to induce a T cell response; Group 3 requires vaccinating a patient at risk of developing a mesothelin-overexpressing tumor

with a polypeptide comprising an MHC Class I-binding epitope of mesothelin in order to induce a T cell response; Group 4 requires vaccinating a patient at risk of developing a mesothelin-overexpressing tumor with a polypeptide comprising an MHC Class II-binding epitope of mesothelin in order to induce a T cell response; Group 5 requires vaccinating a patient having or having had surgically removed a mesothelin-overexpressing tumor with a polynucleotide encoding a polypeptide comprising an MHC Class I-binding epitope of mesothelin in order to induce a T cell response; Group 6 requires vaccinating a patient having or having had surgically removed a mesothelin-overexpressing tumor with a polynucleotide encoding a polypeptide comprising an MHC Class II-binding epitope of mesothelin in order to induce a T cell response; Group 7 requires vaccinating a patient at risk of developing a mesothelin-overexpressing tumor with a polynucleotide encoding a polypeptide comprising an MHC Class I-binding epitope of mesothelin in order to induce a T cell response; Group 8 requires vaccinating a patient at risk of developing a mesothelin-overexpressing tumor with a polynucleotide encoding a polypeptide comprising an MHC Class II-binding epitope of mesothelin in order to induce a T cell response; Group 9 requires vaccinating a patient with a tumor-derived protein, and testing the patient for protein-specific CD4+ or CD8+ T cells in order to determine whether the protein is an anti-cancer vaccine candidate; Group 10 requires vaccinating a patient with a T-cell epitope of mesothelin, and testing the lymphocytes for CD4+ or CD8+ T cell induction in order to determine whether the response can be used as a predictor for long-time survivability using the tumor vaccine; Group 31 requires vaccinating a patient with a tumor vaccine comprising tumor cells,

and testing the patient for delayed type hypersensitivity response to mesothelin in order to determine whether the response can be used as a predictor for long-time survivability using the tumor vaccine; Group 34 requires injecting a mouse with a mouse cell line comprising HPV-16 E6 and E7- and activated oncogene- transformed peritoneal cells to create a tumor, contacting the mouse with a test substance followed by measuring tumor regression, diminution in ascites volume or longer survival in order to determine whether the test substance can be used to treat cancer; and Group 35 requires injecting a mouse with a test substance followed by an injection of a transformed mouse cell line comprising HPV-16 E6 and E7- and activated oncogene- transformed peritoneal cells followed by measuring tumor regression, diminution in ascites volume or longer survival in order to determine whether the test substance can be used to treat cancer. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions Groups 1-10, 31, 34 and 35 are separate and distinct in having different method steps and different endpoints and are patentably distinct.

6. Inventions of Group 15 and Group 1 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polypeptides of Group 15 could be used in a materially different process such as for screening antibodies in immunoassays, eliciting an antibody response, purifying binding

ligands from biological samples or used as a blocking reagent in a binding assay for screening antibodies.

7. Inventions of Group 32 and Group 33 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination (recombinant mouse transformed with mouse peritoneal cell line) as claimed does not require the particulars of the subcombination as claimed because the tumor-bearing mouse can be created by injection with HPV-16 E6 and E7-transformed squamous cell tumors. The subcombination (HPV-16 E6 and E7 transformed peritoneal cells) has separate utility such as a lysate for generating antibodies or for immunoadsorbing anti-tumor antibodies from a sample.

8. Inventions of Group 32 and Group 35 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the transformed peritoneal cell line could be used in a materially different process such as a lysate for producing an antibody or as a vaccine, or for adsorbing tumor specific antibodies from a sample.

9. Inventions of Group 33 and Group 34 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the recombinant mouse model could be used in another materially different process such as for measuring the immune response against the tumor or to obtain tumor-specific antibodies.

10. The products of Groups 11-14 and 16-30 and the methods of Groups 2-10 and 31 are not disclosed in the specification or claimed as capable of being used in combination, therefore, restriction for examination purposes as indicated is proper.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature, restriction for examination purposes as indicated is proper. To search Groups 1-35 together would also present a search burden on the Examiner due to the extensive databases of non-patent literature and because searching the databases is not co-extensive. Thus, Groups 1-35 have been appropriately restricted on the basis of being both distinct and presenting a search burden on the Examiner if they were to be searched together.

12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Elections***

14. If any one of Groups 1, 5, 10, 34 or 35 is elected, then species (tumor) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) ovarian cancer

Specie B) pancreatic cancer

Specie C) mesothelioma:

Specie D) squamous cell carcinoma

The species A-D do not share a common utility nor do they have a substantial structural feature common amongst them. Each of the cancers of species A-D can originate from any number of different cell types (e.g., epithelial, endothelial or mesothelial). Also, the cancers being associated with different organs are nevertheless, under the influence of different growth factors and hormones. Additionally, numerous studies have shown that receptor density and affinity for different therapeutic biomolecules is highly variable amongst different tissues and organs, in addition to there being differences to the extent to which biomolecules are able to penetrate cancers. Thus, species A-D are patentably distinct cancers. Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the cancers having obtained a separate status in the art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 22, and 54 are generic as to species A-D.

15. If any one of Groups 1, 5, 11-13 or 15-17 is elected, then species (mesothelin epitope) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) SLLFLLFSL (SEQ ID NO: 1)

Specie B) VLPLTVAEV (SEQ ID NO: 2)

Specie C) ELAVALAQK (SEQ ID NO: 3)

Specie D) ALQGGGPPY (SEQ ID NO: 4)

Specie E) FYPGYLCSL (SEQ ID NO: 5)

Specie F) LYPKARLAF (SEQ ID NO: 6)

The mesothelin peptide epitopes of species A-F do not share a common core structure or function, thus the species are patentably distinct. One of ordinary skill in the art would appreciate that the amino acid sequences for the peptides was not overlapping or co-extensive, and that each of the peptides might therefore, elicit a distinct and separate clonotypic immune response.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 22, 59, 67 and 77-79 are generic as to species A-F.

16. If any one of Groups 1, 5, 11-13, 17 and 18 is elected, then species (bacterium) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) Shigella flexneri

Specie B) E. coli

Specie C) Listeria monocytogenes

Specie D) Yersinia enterocolitica

Specie E) Salmonella typhimurium

Specie F) Salmonella typhi

Specie G) mycobacterium

The bacterial strains of species A-G do not share a common core structure or function, thus the species are patentably distinct. One of ordinary skill in the art could readily consult any general microbiology textbook describing their different classifications (taxa), genome structures, cell structure and metabolic characteristics, to appreciate that these species are distinct and separate.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 22, 59, 67, 79 and 82 are generic as to species A-G.

17. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

***Conclusion***

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LAB

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER